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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/407,605 | 09/28/1999 | ALLAN M. MILLER | 10278.009001 | 2966 |

7590 08/16/2002

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EXAMINER

KAM, CHIH MIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1653

DATE MAILED: 08/16/2002

169

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/407,605

Applicant(s)

MILLER ET AL.

Examiner

Chih-Min Kam

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-79, 81-94, 96-108, 110-120, 122-125, 127-130 and 132-135 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-66, 68-71, 111, 112, 116-118 is/are rejected.
- 7) ☒ Claim(s) 64-79, 81-94, 96-108, 110-115, 119, 120, 122-125, 127-130 and 132-135 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

4) ☐ Notice of Substantive Examination (PTO-949)

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____

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DETAILED ACTION

1. The finality of the previous office action is withdrawn because a new ground of rejection is applied.

Status of the Claims

2. Claims 64-79, 81-94, 96-108, 110-120, 122-125, 127-130 and 132-135 are pending.

Applicants' amendment filed July 29, 2002 (Paper No. 17) has been entered, and applicants' response has been fully considered. Claims 64, 69, 73, 81, 85, 89, 90, 97-98, 100, 102-104, 113, 114, 116, 119, 120, 125, 130 and 135 have been amended.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 64-79, 81-94, 96-108, 110-115, 119, 120, 122-125, 127-130 and 132-135 under 35 U.S.C.112, first paragraph regarding the fragment thereof or portion thereof, is withdrawn in view of applicants' amendment to the claim and applicants' response at pages 14-15 in Paper No. 17.
4. The previous rejection of claims 64-79, 81-94, 96-108, 110-120, 122-125, 127-130 and 132-135 under 35 U.S.C.112, second paragraph regarding not reciting a specific sequence in the claims, is withdrawn in view of applicants' amendment to the claim and applicants' response at page 15 in Paper No. 17.

Claim Objections

5. Claims 64-79, 81-94, 96-108, 110-115, 119, 120, 122-125, 127-130 and 132-135 are objected to because the claim recites "Table 1" which should not be indicated in the claim

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Table 1 can be shown as a Fig. and recited in the claim to indicate the identity of the common codon encoding an amino acid residue in highly expressed human genes.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 116-118 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 116-118 are directed to a method of making a nucleic acid sequence which directs the synthesis of an optimized message of a human protein of at least 90 amino acids comprising synthesizing at least two fragments of a nucleic acid sequence, wherein the two fragments encode adjoining portions of a human protein of at least 90 amino acids and wherein both fragments are mRNA optimized; and joining the two fragments such that a non-common codon is not created at a junction point, thereby making the mRNA optimized nucleic acid sequence. The specification indicates that the two fragments of a nucleic acid sequence, which encode the adjoining portions of a human protein, are joined together by a fusion (pages 13, lines 9-30). However, the specification does not specify which fragments of a nucleic acid sequence are joined together, and which adjoining portion of the protein are encoded by the fragments. There

portions of the protein which are not encoded by the fragments. Therefore, the specification

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for structure to function/activity, one skilled in the art would not know which portion of the protein is essential for function/activity and how to identify a functional protein. The lack of a structure to function/activity relationship and the lack of representative species for the adjoining portions of the protein as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 64-66, 68-71, 111 and 112 are rejected under 35 U.S.C. 102(a) as anticipated by Kim *et al.* (Gene 199, 293-301 (October 1997)).

Kim *et al.* disclose the usage of selective codons in a given gene is positively correlated with its expression efficiency, and a codon-usage effect on heterologous gene expression in mammalian cells is indicated. Two human erythropoietin (EPO) synthetic genes are generated, one gene (EPO^h) in which native codons were systematically substituted with codons frequently found in highly expressed human genes (Figs. 1 and 2; claims 64-66 and 68-71) and the other gene (EPO^y) with codons prevalent in yeast genes, and the synthetic, mature EPO gene based on either human or yeast high frequency codons were assembled from eight 80-90 base nucleotides

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page 296; claim 111), the expression constructs were transiently transfected into CHO-K1 cell lines, and expressing the human EPO (pages 296-297, Fig 4; claim 112).

Conclusion

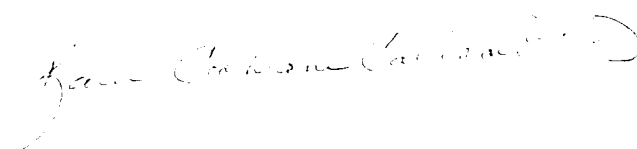
7. No claims are allowed. Claims 64-66, 68-71, 111, 112 and 116-118 are rejected, and claims 64-79, 81-94, 96-108, 110-115, 119, 120, 122-125, 127-130 and 132-135 are objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CHK*
Patent Examiner



August 14, 2002

JOHN COCHRANE CARLSON JR.
PRIMARY EXAMINER